

REMARKS

I. Claim Status

Reconsideration of the present application is respectfully requested. Claims 1-5, 7-10, 12, 13, 16, 19, 20, 22, 33 and 34 are pending. Claims 6, 11, 14, 15, 17, 18, 21, and 23-32 are canceled without prejudice. Claims 13 and 16 have been amended to correct claim dependency. No new matter has been added by way of this amendment.

II. Double Patenting

Claims 1, 2, 3, 5, 7-10, 12, 13, 16, 19, 20, and 22 stand provisionally rejected for nonstatutory obviousness-type double patenting over claims 1, 3-11, and 17 of co-pending application serial no. 10/622,272. According to the Examiner, it would have been obvious to combine the optional ingredients noted in the '272 application to arrive at the presently claimed invention.

Since the rejection is provisional because the allegedly overlapping claims have not yet been patented, to the extent that claim scope overlaps in any patented case, Applicants respectfully submit that the appropriate action will be taken as the Examiner indicates allowable subject matter with regard to the pending rejections under 35 U.S.C. §§ 103(a) and 112.

III. Rejections Under 35 U.S.C. § 112

Claims 4 and 11 stand rejected as unpatentable under 35 U.S.C. § 112, second paragraph, as being indefinite. According to the Examiner, it is unclear if Applicants intend to incorporate octoxyglycerin as an emollient solvent into independent claim 1 since dependent claim 11 is directed to ethyl hexyl glycerin, which the Examiner contends is octoxyglycerin. Thus, the Examiner alleges that it is not clear if Applicants claim octoxyglycerin twice in the instant composition.

Without conceding to the Examiner's contention, and to further the prosecution of the instant application, Applicants have canceled claim 11 and request that the rejection be withdrawn.

Claims 13 and 16 stand rejected as unpatentable under 35 U.S.C. § 112, second paragraph, as being indefinite. According to the Examiner, the claims are indefinite because they depend from canceled claim 6. Applicants have amended claim 13 to depend from claim 1, and assert that in view of the amendment, claims 13 and 16 are definite. This amendment is supported by the original claims as filed. As noted above, no new matter is added by way of this amendment. Accordingly, Applicants respectfully request that the rejection be withdrawn.

IV. Rejections Under 35 U.S.C. § 103(a)

U.S. Patent No. 5,965,610 to Modak et al. in view of U.S. Patent No. 5,736,574 to Burnier et al.

Claims 1-3, 5, 7, 9, 19, 20, 22, 33 and 34 stand rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,965,610 (to Modak et al.) in view of U.S. Patent No. 5,736,574 (to Burnier et al.). The Examiner contends that Modak discloses a topical gel composition comprising zinc gluconate, a solvent (*i.e.*, water or alcohol), a thickening agent, a hydrophobic polymer, an emulsifying agent, an emollient, an antioxidant and an antimicrobial as encompassed by the pending claims. The Examiner further alleges that Burnier discloses synergistic antimicrobial combinations comprising N-n-octanoglycine and octoxyglycerin which are suitable for a wide variety of pharmaceutical and cosmetic compositions. According to the Examiner, it would have been obvious to one of ordinary skill in the art to combine the antimicrobial mixtures of Burnier with the composition of Modak, which allegedly describes the claimed invention.

Applicants respectfully disagree. To support an assertion of obviousness, the Examiner must show that “all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination yielded nothing more than predictable results to one of ordinary skill in the art.” M.P.E.P § 2143. *See also KSR International Co. v. Teleflex Inc.*, 550 U.S. 398,127 S. Ct. 1727 (U.S. 2007), 82 USPQ2d at 1395.

Applicants submit that the cited art does not provide all requisites for rendering the claimed invention obvious because the cited art, considered separately or in combination, fails to provide a skilled artisan with a reasonable expectation of successfully practicing the claimed invention. The claims as amended are directed to a hydroalcoholic gel composition comprising

antimicrobially synergistic amounts of octoxyglycerin and an antimicrobial agent, among other ingredients. As discussed in the response to final office action filed August 13, 2008, and as disclosed in Example 1 of the instant application (*see pp. 34-36*), compositions comprising either octoxyglycerol (*i.e.* Sensiva SC50) or benzalkonium chloride (“BZK”) alone were ineffective against *S. aureus*, but when present together in a single composition, the composition exhibited a surprisingly strong and unexpected antimicrobially synergistic effect against *S. aureus*.

Tables 1 and 2 show that no significant antimicrobial activity against *S. aureus* was obtained with 2-5 percent [octoxyglycerol]. . . Similarly, 0.12 and 0.19 percent BZK exhibited minimal or no antimicrobial activity (Table 2). However, combinations of 1-2 percent Sensiva SC50 and 0.12-0.19 percent BZK showed 5000-33000 fold reduction in colony-forming units compared to control values (Table 2).

See the specification, Example 1, at p. 36, ¶60.

In contrast to the composition encompassed by the claims of the instant application, Applicants submit that a skilled artisan would have no expectation of successfully combining the ingredients of Modak and Burnier to arrive at the claimed invention. Burnier describes a composition comprising antimicrobially synergistic amounts of a glyceryl monoalkyl ether and at least one antimicrobial hydrolipid and/or lipid. *See* Burnier, abstract. Modak is directed to a composition for inactivating irritants in fluids which comprises an irritant-inactivating agent (*e.g.*, an antimicrobial, *see* Modak at Col. 4, ll. 57-59), and a substance that prevents the irritant-inactivating agent from binding to a surface, for example, skin. *See* Modak at Col. 2, ll. 29-45.

According to Modak, the use of antimicrobial agents in antiseptic hand washes or to coat physical barriers, for example, a glove, for protection against bodily fluids containing infectious microbial pathogens has limited utility due to absorption of the antimicrobial agents into the skin or glove. *See* Modak at Col. ll. 30-51. By combining the antimicrobial with an agent that prevents absorption of the antimicrobial (*e.g.*, a zinc compound, *see* Modak at Col. 7, ll. 25-41), Modak discloses compositions which can rapidly inactivate microbes present in body fluids that come into contact with the composition, while also preventing absorption of the antimicrobial composition to a surface, such as a hand or glove.

In particular, Modak discloses that various metal salts were evaluated in combination with irritant-inactivating agents, and zinc gluconate, unlike other salts tested, was surprisingly

found to form a gel matrix when mixed with water or alcohol. Furthermore, when zinc gluconate was combined with the antimicrobial chlorhexidine, the composition inactivated irritants present in fluids without binding to a surface (*i.e.*, a hand). *See* Modak at Col 7, ll. 24-41. In addition, Applicants note that in Modak's Examples, compositions comprising the antimicrobial chlorhexidine combined with surface binding inhibitors (*e.g.*, zinc salts), are the only antimicrobial compositions tested for their ability to inactivate irritants without binding to a surface. *See* Examples 20-26 of Modak at Col. 20-24. Modak does not suggest or describe a composition comprising octoxyglycerin or an antimicrobial synergistic effect between octoxyglycerin and an antimicrobial agent. Thus, in view of Modak, a skilled artisan would have no expectation that all irritant-inactivating agents (*i.e.*, any antimicrobial agents) could be mixed in any combination with any surface binding inhibitor; rather, the skilled artisan would only expect the combinations disclosed by Modak (*i.e.*, those comprising the antimicrobial chlorhexidine) to successfully inactivate irritants present in a bodily fluid while remaining unbound to a surface (*i.e.*, skin or a physical barrier).

Applicants also note that Modak does not suggest or describe antimicrobial compositions comprising Burnier's hydrolipid and lipid antimicrobials, and further, does not suggest or describe that such antimicrobials can rapidly inactivate irritants while simultaneously being inhibited from binding a surface when combined with a surface binding inhibitor. As such, a skilled artisan would have no expectation that the antimicrobials disclosed by Burnier could be successfully used in Modak's formulations as a sanitizer for hands or coating of a physical barrier. Rather, in view of Modak, a skilled artisan would at best limit the irritant-inactivating compounds to those disclosed by Modak that successfully inactivated irritants without binding to a surface (*i.e.*, chlorhexidine agents).

Second, Applicants submit that the combined teaching of Modak and Burnier fails to describe a composition as presently claimed. In particular, the claims recite a composition having a viscosity below 2000 centipoises. Both Modak and Burnier are silent with regard to the viscosity of their disclosed compositions, and as such, the composition defined by the combined teaching of the two references fails to describe all the elements of the presently claimed invention.

For the reasons described above, Applicants submit that a skilled artisan, in view of the cited references, would have no expectation of successfully practicing the claimed invention, and

further, because the combined teaching of the cited art does not describe all the elements of the claims as amended, the claims are not obvious over Modak and Burnier. Applicants respectfully request that the rejection be withdrawn.

V. Conclusion

In view of the above amendments and remarks, it is respectfully requested that the application be allowed and passed to issue. If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below. Applicants believe that no additional fees are due at this time. However, if any fees are required, the Commissioner is authorized to charge such fee to Deposit Account No. 02-4377.

Respectfully submitted,
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